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September 22, 2006

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit 1633**

**Attn: Mail Stop Amendment**

Re: U.S. Utility Patent Application  
Application No. 10/618,299; Filed: July 11, 2003  
For: **Method of Enhancing Delivery of a Therapeutic Nucleic Acid**  
Inventors: Barsoum *et al.*  
Our Ref: 2159.0830001/EJH/SAS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Credit Card Payment Form (PTO-2038) in the amount of \$180.00 to cover the Information Disclosure Statement fee;
2. First Supplemental Information Disclosure Statement;
3. One (1) page of Form PTO/SB/08A citing two (2) documents (US1-US2);
4. Two (2) pages of Form PTO/SB/08B citing eighteen (18) documents (NPL1-NPL18);
5. Copies of eighteen (18) cited documents (NPL1-NPL18); and
6. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.


8

Commissioner for Patents  
September 22, 2006  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Elizabeth J. Haanes", written in a cursive style.

Elizabeth J. Haanes, Ph.D.  
Attorney for Applicants  
Registration No. 42,613

EJH/SAS:dms  
Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Barsoum *et al.*

Appl. No.: 10/618,299

Filed: July 11, 2003

For: **Method of Enhancing Delivery of a  
Therapeutic Nucleic Acid**

Confirmation No.: 6907

Art Unit: 1633

Examiner: Robert M. Kelly

Atty. Docket: 2159.0830001/EJH/SAS

**First Supplemental Information Disclosure Statement  
Under 37 C.F.R. § 1.97(c)**

*Mail Stop Amendment*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **NPL1** to **NPL18** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, **US1** to **US2**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

The Examiner's attention is directed to the related issued Patent No. 6,696,423 (Document **US1**) and the following co-pending U.S. Patent Application, which is directed to related technical subject matter:

Application No. 10/395,712, inventors James G. Barsoum, *et al.*, filed March 20, 2003; published on December 11, 2003 as U.S. Publication No 2003/0229042 A1 (Document **US2**).

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The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. Attached is out PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



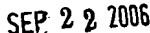
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Date:

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Sheet	1	of	1
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## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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## FOREIGN PATENT DOCUMENTS

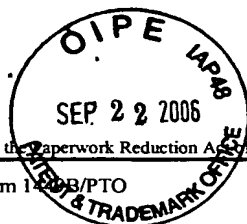
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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

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				Application Number	10/618,299
				Filing Date	July 11, 2003
				First Named Inventor	James G. Barsoum
				Art Unit	1633
				Examiner Name	Robert M. Kelly
Sheet	1	of	2	Attorney Docket Number	2159.0830001/EJH/SAS

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	NPL1	Brunner, K.T., <i>et al.</i> , "Blood Clearance of P <sub>32</sub> -Labeled Vesicular Stomatitis and NewCastle Disease Viruses by the Reticuloendothelial System in Mice," <i>J. Immunol.</i> , 85:99-105, American Association of Immunologists (1960)	
	NPL2	Cai, P., <i>et al.</i> , "Methyl palmitate: Inhibitor of phagocytosis in primary rat Kupffer cells," <i>Toxicol.</i> 210:197-204, Elsevier Ireland Ltd. (June 2005)	
	NPL3	Dachs, G.U., <i>et al.</i> , "Targeting Gene Therapy to Cancer: a Review," <i>Oncol. Res.</i> 9:313-325, Cognizant Communication Corporation (1997)	
	NPL4	Fahimi, H.D., "The Fine Structural Localization of Endogenous and Exogenous Peroxidase Activity in Kupffer Cells of Rat Liver," <i>J. Cell Biol.</i> 47:247-262, Rockefeller University Press (1970)	
	NPL5	Kirn, A., <i>et al.</i> , "Uptake of Viruses by Kupffer Cells Isolated from Human Liver," <i>Lancet North Am. Ed.</i> 2:585-586, Lancet Publishing Group (1980)	
	NPL6	Kolb-Bachofen, V., "Uptake of Toxic Silica Particles by Isolated Rat Liver Macrophages (Kupffer Cells) Is Receptor Mediated and Can Be Blocked by Competition," <i>J. Clin. Invest.</i> 90:1819-1824, The American Society for Clinical Investigation, Inc. (1992)	
	NPL7	Laurent, N., <i>et al.</i> , "Uptake by rat liver and intracellular fate of plasmid DNA complexed with poly-L-lysine or poly-D-lysine," <i>FEBS Lett.</i> 443:61-65, Federation of European Biochemical Societies (1999)	
	NPL8	Kuzmin, A.I., <i>et al.</i> , "Macrophage depletion increases the safety, efficacy and persistence of adenovirus-mediated gene transfer in vivo," <i>Gene Ther.</i> 4:309-316, Stockton Press (1997)	
	NPL9	Marianneau, P., <i>et al.</i> , "Infection of Primary Cultures of Human Kupffer Cells by Dengue Virus: No Viral Progeny Synthesis, but Cytokine Production Is Evident," <i>J. Virol.</i> 73:5201-5206, American Society for Microbiology (1999)	
	NPL10	McCuskey, R.S., <i>et al.</i> , "Kupffer Cell Function in Host Defense," <i>Rev. Infect. Dis.</i> 9:S616-S619, The University of Chicago (1987)	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				Application Number	10/618,299
				Filing Date	July 11, 2003
				First Named Inventor	James G. Barsoum
				Art Unit	1633
				Examiner Name	Robert M. Kelly
Sheet	2	of	2	Attorney Docket Number	2159.0830001/EJH/SAS

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL11	Miller, N., and Vile, R., "Targeted vectors for gene therapy," <i>FASEB J.</i> 9:190-199, The Federation of American Societies for Experimental Biology (1995)	
	NPL12	Mogensen, S.C., "Macrophages and Age-Dependent Resistance to Hepatitis Induced by Herpes Simplex Virus Type 2 in Mice," <i>Infect. Immun.</i> 19:46-50, American Society for Microbiology (1978)	
	NPL13	Rentsch, M., <i>et al.</i> , "Benefit of Kupffer cell modulation with glycine versus Kupffer cell depletion after liver transplantation in the rat: effects on postischemic reperfusion injury, apoptotic cell death graft regeneration and survival," <i>Transpl. Int.</i> 18:1079-1089, European Society for Organ Transplantation (September 2005)	
	NPL14	Rubin, D.H., <i>et al.</i> , "Transport of Infectious Reovirus into Bile: Class II Major Histocompatibility Antigen-Bearing Cells Determine Reovirus Transport," <i>J. Virol</i> 61:3222-3226, American Society for Microbiology (1987)	
	NPL15	Selgrade, M.K., and Osborn, J.E., "Role of Macrophages in Resistance to Murine Cytomegalovirus," <i>Infect. Immun.</i> 10:1383-1390, American Society for Microbiology (1974)	
	NPL16	van Til, N.P., <i>et al.</i> , "Kupffer Cells and Not Liver Sinusoidal Endothelial Cells Prevent Lentiviral Transduction of Hepatocytes," <i>Mol. Ther.</i> 11:26-34, The American Society of Gene Therapy (January 2005)	
	NPL17	Wake, K., <i>et al.</i> , "Cell Biology and Kinetics of Kupffer Cells in the Liver," <i>Int. Rev. Cytol.</i> 118:173-229, Academic Press, Inc. (1989)	
	NPL18	Zenilman, M.E., <i>et al.</i> , "Use of Ricin A-Chain to Selectively Deplete Kupffer Cells," <i>J. Surg. Res.</i> 45:82-89, Academic Press, Inc. (1988)	

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